

DEPARTMENT OF HEALTH

NOTICE OF EMERGENCY RULEMAKING

The Director of the Department of Health, pursuant to the authority set forth under § 302 (14) of the District of Columbia Health Occupation Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1203.02 (14)) ("Act"), and Mayor's Order 98-140, dated August 20, 1998, and The Pharmacy Practice Emergency Amendment Act of 2008, effective December 8, 2008 (D.C. Act 17-0596); gives notice of the adoption on an emergency basis of an amendment to chapter 65 of Title 17 of the District of Columbia Municipal Regulations (DCMR) (Pharmacists) by adding a new § 6512 and amending § 6599.1 to add definitions for the terms ACPE, Administer, Immunization, Vaccination, and Written protocol.

This emergency rulemaking will permit pharmacists licensed in the District of Columbia and certified to administer immunizations and vaccinations by the Board of Pharmacy, to administer influenza vaccinations upon receipt of a written physician protocol and a valid prescription or physician standing order; and to administer emergency anaphylactic reaction treatment pursuant to an approved physician-pharmacist protocol.

This emergency action is based on the demonstrated health benefit of immunizations and vaccinations, the threat of an impending influenza season, and the statistical data that individuals who reside in states where pharmacists are allowed to administer immunizations and vaccinations are 10.6% more likely to be immunized than individuals who live in states where pharmacists cannot administer immunizations and vaccinations. This emergency rule was adopted on January 9, 2009, and became effective immediately on that date

The emergency rule will expire on March 8, 2009, or upon publication of a Notice of Final Rulemaking in the D.C. Register, whichever occurs first.

6512 ADMINISTRATION OF IMMUNIZATIONS AND VACCINATIONS BY PHARMACISTS

6512.1 A pharmacist shall not administer immunizations and vaccinations unless certified by the Board of Pharmacy in accordance with this section to do so.

6512.2 An applicant for certification to administer immunizations and vaccinations shall do the following:

(a) Submit a completed application and pay the required fee;

(b) Demonstrate to the satisfaction of the Board that he or she:

(1) Is licensed in good standing under the Act to practice pharmacy;

- (2) Possesses an active certification in cardiopulmonary resuscitation for health care providers; and
- (3) Has successfully completed an ACPE approved course approved by the Board of Pharmacy which:
 - (i) Is evidence-based;
 - (ii) Includes study material;
 - (iii) Includes hands-on training in techniques for administering immunizations or vaccines;
 - (iv) Requires testing with a passing score;
 - (v) Meets current Center for Disease Control and Prevention training guidelines; and
 - (vi) Provides a minimum of twenty (20) hours of instruction and hands-on training in:
 - (A) Basic immunology and vaccine protection;
 - (B) Vaccine-preventable diseases;
 - (C) Vaccine storage and management;
 - (D) Informed consent;
 - (E) Physiology and techniques for vaccine administration;
 - (F) Pre and post-vaccine assessment and counseling;
 - (G) Immunization record management; and
 - (H) Identification, appropriate response, documentation, and reporting of adverse events.

6512.3 A pharmacist certified by the Board to administer immunizations and vaccinations shall:

- (a) Maintain current certification in cardiopulmonary resuscitation for health care providers;

- (b) Complete two (2) hours of continuing education each renewal period relevant to the administration of immunizations and vaccinations, in addition to the continuing education credits required under subsection 6513.4 of this chapter and submit proof upon request to the Board; and
 - (c) Administer vaccines and immunizations in accordance with CDC guidelines.
- 6512.4 The location in the pharmacy where vaccinations and immunizations are administered shall:
 - (a) Ensure privacy;
 - (b) Be maintained to promote an aseptic environment;
 - (c) Have adequate telecommunications devices to summon aid and communicate emergency situations; and
 - (d) Have adequate equipment and supplies to respond to adverse events and emergency situations
- 6512.5 A pharmacist certified by the Board to administer immunizations and vaccinations shall only administer immunizations and vaccinations pursuant to:
 - (a) A written protocol signed and dated by a District of Columbia licensed physician authorizing the administration upon receipt of a written protocol; and
 - (b) A valid prescription; or
 - (c) Physician standing order
- 6512.6 A copy of the written protocol required in § 6512.5 shall be maintained by the administering pharmacist at the pharmacy practice site and readily available for inspection upon request of the Board of Pharmacy or submitted to the Board for review upon request.
- 6512.7 The written protocol shall contain, at a minimum, the following:
 - (a) A statement identifying the individual physician authorized to prescribe drugs and responsible for the delegation of administration of immunizations or vaccinations;
 - (b) A statement identifying the individual pharmacist(s) authorized to administer immunizations or vaccinations as delegated by the physician;

- (c) A statement identifying the patient or groups of patients to receive the authorized immunization or vaccination; which shall be limited to:
- (1) Patients who are currently under the individual physician's care or with whom the physician has provided medical treatment or care within the twelve months prior to the date of the written protocol;
 - (2) Patients who are currently under the practice's care or with whom a physician within the practice has provided medical treatment or care within the twelve months prior to the date of the written protocol;
 - (3) Residents of a health care, residential services, or assisted living facility, when the medical director of such facility is the physician making the delegation;
 - (4) District resident populations identified by the Director of the Department of Health as part of a public health services program, when the Director, or his or her designee, is the physician making the delegation; and
 - (5) Inmates of the District of Columbia jail, when the medical director for the facility is the physician making the delegation.
- (d) A statement identifying the location(s) at which the pharmacist may administer immunizations or vaccinations which shall not include where a patient resides, except for a licensed nursing home, residential care facility, assisted living center, the District of Columbia jail, or a hospital;
- (e) A statement identifying the immunizations and vaccinations that may be administered by the pharmacist, which shall be limited to the list of approved vaccinations set forth in § 6512.19 of this chapter;
- (f) A statement identifying the activities the pharmacist shall follow in the course of administering immunizations and vaccinations, including procedures to follow in the case of reactions following administration; and
- (g) A statement that describes the content of, and the appropriate mechanisms for the pharmacist to report the administration of immunizations and vaccinations to the physician issuing the written protocol within the time frames specified in the protocol.

6512.8 The pharmacist shall review the written protocol annually with the physician.

6512.9 Except as provided in § 6512.10, a pharmacist certified by the Board to administer immunizations and vaccinations shall not administer an immunization or vaccination to any individual younger than eighteen (18) years old and must

obtain acceptable proof of age before administration.

- 6512.10 A pharmacist certified by the Board to administer immunizations and vaccinations shall only administer an immunization or vaccination to an individual under the age of eighteen (18) upon a referral from a physician who has an established physician-patient relationship with the patient.
- 6512.11 Except as provided in § 6512.12, a pharmacist certified to administer immunizations and vaccinations shall not delegate any function or duty, in part or in whole, pertaining to the administration of immunizations and vaccinations.
- 6512.12 A pharmacist certified to administer immunizations and vaccinations may permit a pharmacy student in a pharmacy experiential program, who has successfully completed a Board-approved certification course to administer influenza vaccinations under the pharmacist's direct supervision to an individual who is eighteen (18) years of age or older.
- 6512.13 Every patient receiving an immunization or vaccination by a pharmacist certified to do so, shall be provided with a current vaccine information statement.
- 6512.14 The pharmacist shall obtain the patient's informed written consent prior to administering the immunization or vaccination.
- 6512.15 As part of the informed consent, the practitioner and the pharmacist shall provide written disclosure to the patient of any contractual arrangement with any other party or any financial incentive that may impact one of the party's decisions to participate in the agreement.
- 6512.16 The pharmacist shall maintain a copy of the patient's informed written consent on file at the pharmacy practice site where the administration was given for a period of two (2) years after the date of administration.
- 6512.17 The pharmacist shall maintain documentation at the pharmacy practice site where the immunization or vaccination was administered for a period of two (2) years that includes:
- (a) The name, address, gender, allergies and date of birth of the individual receiving the immunization or vaccination;
 - (b) The date of administration
 - (c) The route and site of the immunization or vaccination;
 - (d) The name, dose, manufacturer's lot number, and expiration date of the vaccine;

- (e) The name and address of the primary health care provider of the individual receiving the immunization or vaccination as identified to the pharmacist by that individual;
- (f) The date on which the vaccination or immunization information was reported to the delegating physician;
- (g) The name of the pharmacist administering the immunization or vaccination;
- (h) The version of the vaccination information statement provided to the patient;
- (i) A copy of the signed patient informed consent form; and
- (j) Any adverse events encountered.

6512.18 The records required to be maintain pursuant to this chapter shall be readily available for inspection upon request of the Board of Pharmacy or submitted to the Board for review upon request.

6512.19 A pharmacist certified under this chapter may administer influenza vaccinations and emergency anaphylactic reaction treatment pursuant to a written protocol signed and dated by a District of Columbia licensed physician.

Section 6599.1 is amended as follows:

a) The following terms with the ascribed meanings are added as follows:

ACPE— The Accreditation Council for Pharmacy Education.

Administer— The direct application of a prescription drug by injection, inhalation, ingestions, or any other means to the body of a patient

Immunization— The act of inducing antibody formation, thus leading to immunity.

Vaccination— Administration of any antigen in order to induce immunity; is not synonymous with immunization since vaccination does not imply success.

Written protocol— a specific written plan for a course of medical treatment containing a written set of specific directions created by the physician for one or more patients.